DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

November 7, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 – 05

Daniel E. Dallmann
President
Dallmann Farms, Inc.
N6038 East River Road
Brillion, Wisconsin 54110

Dear Mr. Dallmann:

On June 13, 18 and July 2, 2003, an investigator from the Food and Drug Administration (FDA) conducted an inspection at your dairy operation located in Brillion, WI. That inspection confirmed that you offered two dairy cows for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You also caused the adulteration of an animal drug because the drug was used in a manner that does not conform to its approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 CFR 530, copy enclosed). This caused the animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about March 18, 2003, you sold a cow, identified with back tag number 35 ME 1975 for slaughter as human food through [redacted] The animal was sold to and slaughtered by [redacted] United States Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 1.36 ppm gentamicin in the liver and 19.12 ppm gentamicin in the kidney. No tolerance has been established for residues of gentamicin in the edible tissues of cattle (21 CFR 556.300, copy enclosed). USDA analysis also identified the presence of 1.28 ppm penicillin in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle (21 CFR 556.510, copy enclosed). The presence of these drugs in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about May 20, 2003, you sold a cow, identified with back tag number 35 ME 2760, for slaughter as human food through [redacted] The animal was sold to and slaughtered by [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 3.23 ppm gentamicin in the kidney. No tolerance has been established for residues of gentamicin in the edible tissues of cattle (21 CFR 556.300, copy enclosed). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example, you do not maintain medication records to avoid unsafe residues. You also lack an adequate system for assuring that drugs are not used in a manner contrary to the labeled directions and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

You adulterated gentamicin sulfate solution within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the approved conditions of use or the extralabel use regulations at 21 CFR Part 530. Gentamicin is not approved for use in dairy cattle. You stated that you sometimes administer gentamicin to treat severe pneumonia in cows. This use of gentamicin is contrary to the approved conditions of use. Such an extralabel use is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in conformance with other criteria set forth in 21 CFR 530, including that there may be no residue which may present a risk to the public health. A veterinarian prescribed gentamicin for extralabel use to treat mastitis in your dairy cows. Because your use of gentamicin was outside of this prescribed use and, therefore, was not on the order of a licensed veterinarian, your use of the drug was not in compliance with extralabel use regulations, in particular 21 CFR 530.10 and 530.11(a). As a result, your use of this drug caused it to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action (such as seizure or injunction) without further notice to you.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be held responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your dairy operation into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosures: 21 CFR 530
21 CFR 556.300
21 CFR 556.510

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